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EXAMINER

GABEL, GAILENE

ART UNIT PAPER NUMBER

1641

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/550,276
Filing Date: April 15, 2000
Appellant(s): SPAULDING, GLENN F.

COE F. MILES
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 17, 2005.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

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The rejection of claims 1-4, 10, 11, 13-31, and 33-34 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

US 5,582,795	NISHINA et al.	10 December 1996
US 5,352,879	MILCH	04 October 1994
US 5,126,554	IZUMI	30 June 1992
US 6,254,834	ANDERSON et al.	3 July 2001

SURMODICS INC., Eden Prairie, Minnesota: Applicant's admitted prior art at page 5, Example 2 of the specification.

(10) *Grounds of Rejection*

I. Rejections Withdrawn:

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being vague and indefinite for reciting, "a barcode adapted to be interrogated" is, hereby, withdrawn.

II. The following grounds of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are drawn to a cytometer having a rotating means that rotates a transparent cylinder, a light source that illuminates the transparent cylinder while it rotates, a detector that detects light signal from the transparent cylinder while it rotates, a determining means that determines at least one cytometric characteristic of the sample disposed in the sample, and a movement means for moving the transparent cylinder, the light source, and the detector in a longitudinal axis relative to one another. The determining means as recited reads on a barcode reader that scans barcode labels affixed on the outside of a transparent cylinder to decode information incorporated into the barcode label, since the claims are not limited to scanning contents within the containment of the transparent cylinder to obtain cytometric characteristics therefrom. Hence, cytometric characteristics can be information incorporated about a [patient] sample, into a barcode label. In the hospital setting, barcode labels are used in

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identifying blood collected from patients and include information such as patient's name, social security number, age, blood type, i.e. B positive which describes a presence of B and Rh antigens in the blood cells of the patient, and diagnosis, i.e. acute myelocytic leukemia, which provides information that a patient's white blood cell count is high and have cytometric characteristics that includes large granular young myelocytic and blast cells, or sickle cell anemia which provides information that some of patient's red blood cells are characteristically sickled or S-shaped. Accordingly,

A) Claims 1, 2, 10, 11, 21, 22, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishina et al. (US Patent 5,582,795).

Nishina et al. disclose a hold-transfer system or apparatus for use in analyzing fluids such as blood and medicines (see column 1, lines 6-9). The apparatus comprises a rotating means (stepper motor) which receives and rotates transparent cylinders (test tubes) about the longitudinal axis of the transparent cylinder. Transparent guards are installed for protection of transparent cylinders. The apparatus has a light source such as laser or light emitting diode (LED) which illuminates a portion of the transparent cylinder (barcode) while the transparent cylinder is being rotated. The apparatus further comprises a detector and determining means (automatic scanning type barcode reader) which detects light signal provided by the light source and reflected from the barcode while the transparent cylinder is being rotated. The barcode reader determines information encompassing cytometric characteristics incorporated into a barcode label, on a sample disposed in the transparent cylinder (see column 3, line 45 to column 4, lines 19, and column 5, lines 4-20). The apparatus also includes a movement means

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(first and second motors) for moving the transparent cylinder, the light source and barcode reader along a longitudinal axis relative to one another (see column 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

B) Claims 24, 25, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Milch (US Patent 5,352,879).

Nishina et al. has been discussed supra. Nishina et al. is silent in teaching that a detector (such as a barcode reader) comprises an analog to digital converter, a photomultiplier tube, and a processing means.

Milch discloses a detector means (barcode reader) that reads optically encoded information on a barcode label. The detector means comprises an analog to digital converter, a photomultiplier tube (two photodetectors), and processing means (control means or CPU) (see claims 4 and 5 of Milch et al.).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the analog to digital converter, photomultiplier tube, and processing means as taught by Milch into the barcode reader of Nishina because digital

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converters, photomultiplier tubes, and processing means constitute obvious features which are routinely known in the art as being part of a barcode reader.

C) Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Izumi (US Patent 5,126,554).

Nishina et al has been discussed supra. Nishina et al. differ from the instant invention in failing to disclose that the detector comprises a charge-coupled device (CCD).

Izumi discloses a detector (barcode reader) for use in reading barcode symbols. According to Izumi, the detector comprises a CCD. (See claim 3 of Izumi).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the CCD as taught by Izumi into the barcode reader of Nishina because CCDs constitute an obvious feature which is routinely known in the art as being part of a barcode reader.

D) Claims 3, 13-18, 26-28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Anderson et al. (US 6,254,834).

Nishina et al has been discussed supra. Nishina et al. differ from the instant invention in failing to disclose that the transparent cylinder (which has a closed end and an open end) includes a cell guide member and has organic photoreceptor and

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standards affixed thereon. Nishina et al. further differ in failing to disclose that the apparatus has more than one light source.

Anderson et al. disclose a cytometric apparatus or system for characterizing microorganisms such as bacteria, virus, mycoplasma, or yeast cells in a sample contained in a transparent cylinder (centrifuge tube) (see column 10, lines 22-45). The transparent cylinder has an open end (upper region), a middle cell guide member, and a closed end (lower region) with successively smaller diameters (see columns 4-5). The open end is for receiving a sample which can be plugged with a sealing cap and the lower end is a tubular microbanding region for isopycnicly banding all the infectious particles or cells in the presence of a fluorescent dye or a combination of fluorescent dyes. Anderson et al. disclose that the inner surface of the cylinder can be modified by treatment with non-absorptive material (see column 5). Anderson et al. also teach affixing standards into the transparent cylinder (see Example). Anderson et al. provide use of the apparatus in combination with one or more light sources emitting at different wavelengths and detection systems, i.e. diffraction grating (see column 7, lines 32-41 and column 10, lines 8-21 and 46-67). The optical signal detected from the microbanding is processed in a processing means (computer).

It would have been obvious to incorporate a cell guide member having organic photoreceptor and standards affixed thereon as taught by Anderson into the apparatus of Nishina because Nishina specifically taught that the adapters upon which the transparent cylinders are disposed can come in various shapes to accommodate for any change in shape or configuration of a transparent cylinder (see column 6, lines 1-14),

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such as for example those that have incorporated thereto, cell guides having successively smaller diameter towards the lower end of the transparent cylinder such as taught by Anderson.

E) Claims 4, 19, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Anderson et al. (US 6,254,834) as applied to claims 13-18, 26-28; and 31 above, and further in view of Surmodics, Inc..

Nishina et al. and Anderson et al. have been discussed supra. Nishina et al. and Anderson et al. differ from the instant invention in failing to disclose dibromo anthanthrone which is an organic photoreceptor material activated by a wavelength of approximately 300 nm to 100 nm.

Applicant, by way of disclosure at page 5, lines 17-22, admits that incorporation of photo cross-linking agents into the inner wall of cylinders, is known and used commercially by Surmodics, Inc. These photo-crosslinking agents include organic photoreceptor materials optimized for 300 nm - 2000 nm such as dibromo anthanthrone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the immobilized reagents in the transparent cylinders taught by Anderson used in the apparatus of Nishina to include or otherwise substitute the photoreceptor materials, i.e. chromogenic materials and luminescent materials, with dibromo anthanthrone, because SurModics specifically taught its application and suitability on inner walls of cylinders such as those used by Anderson for application in

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the device of Anderson. Further, the parameters set forth in claims 19 and 23 wherein "(the photoreceptor material) is activated by a wavelength of approximately 300 nm - 100 nm", constitute result effective variables which Surmodics, Inc. has shown may be obtained by optimization procedures. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of *Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." *Id.* at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of *Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 19 and 23 are for any particular purpose or solve any stated problem and the prior art teaches that photoreceptor materials often vary according to specific application or purpose or the sample being analyzed, the various detection materials and parametric requirements appear to work equally as well. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable range for dibromo anthanthrone as disclosed by the prior art by normal optimization procedures.

III. Allowable Subject Matter

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In an effort to guide Appellant to direction of allowable subject matter and recitation of patentable claims that do not read on prior art cited, claim language was offered and suggested by the Office. As discussed with Appellant's Representative, amendment of claims 1 and 10 to recite, "a determining means for determining at least one cytometric characteristic from a sample contained or dispersed within said transparent cylinder" would have been allowable and would have obviated all prior art rejections, as such would have been structurally distinct and manipulatively different from Nishina's apparatus having a light source and photodetector adapted to interrogate a barcode on the outside of a tube to determine information incorporated thereto, such as information about [patient] blood samples such as blood type which is encompassed within the scope of Appellant's description of cytometric characteristics. Appellant provided statements on the record throughout the Brief and throughout the specification that limits the determining means to determining cytometric characteristics from a sample contained or dispersed within the transparent cylinder. The language is consonant with Appellant's argument in page 5, lines 4-8 and page 6, lines 9-11 which states that in Appellant's cytometer, "[A light source and photodetector] ... interrogates the cells located inside of the container" and page 11, lines 26-27 which states, Appellant's cytometer "[is] used to determine a cytometric characteristic of the liquid within the container". Such language is further consonant with Appellant's description in the disclosure of his invention at page 3, lines 30-35 which provides that "the entire inside wall of the container is scanned" and "[I]ncrementally scanning each level yields information on cells that have been distributed along the inner surface of the wall", and

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at page 5, lines 33-35 which provides that [A] light source such as LED or laser and a photodetector are adapted to interrogate cells that are dispersed to the inner surface of the wall of the cylinder . Assistance was offered to Appellant as it is the function of the Office to delimit the coverage of Appellants claims to encompass their invention as described in the specification and as stated by Appellant clearly on the record, and to exercise patent protection by excluding coverage outside of their invention and entitlement.

In the telephone interview on May 26, 2005, however, Appellant s Representative reiterated that the claims as currently recited, are allowable over the prior art cited and hence, graciously declined the Office s suggestion, in favor of their decision to take the case to the board for decision.

(11) Response to Argument

A) Appellant argues that Nishina does not disclose or suggest determining a cytometric characteristic of a sample disposed in a transparent cylinder . Appellant specifically contends that Nishina does not teach every element contained in the claims because it fails to determine a cytometric characteristic of the liquid [from] within his extraction container.

In response, Nishina reads on the claimed invention, specifically claims 1 and 10 because both claims are not limited to *determining a cytometric characteristic from the sample which is contained and dispersed within the transparent cylinder* which is

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Appellant's invention as taught and encompassed within Appellant's disclosure and argued by Appellant throughout his responses. Indeed, Nishina teaches determining a cytometric characteristic of a sample disposed in a transparent cylinder as recited in claims 1 and 10 because it reads on determining information incorporated into a barcode label including patient name, blood type (cytometric characteristic), diagnosis of a blood related disease such as multiple myeloma (rouleaux formation of erythrocytes- cytometric characteristic), etc. which in laboratory and hospital setting, are required patient information in a barcode label. Alternatively, the Office concurs that Nishina does not teach *determining a cytometric characteristic from the sample which is contained and dispersed within the transparent cylinder*, which is language supported throughout Appellant's disclosure and arguments in the Appeal Brief, but not reflected and recited in the rejected claims.

B) Appellant argues that there is a distinction between reading a barcode affixed to a container and determining a cytometric characteristic of a sample disposed in a container because the act of reading the barcode (affixed outside the tube which is properly faced outward) is different from the act of determining cytometric characteristics of a sample in the tube, as claimed.

In response, the Office concurs that reading a barcode affixed to a container as taught by Nishina is distinct from *determining a cytometric characteristic from the sample which is contained and dispersed within the transparent cylinder*, which is language suggested to Appellant by the Office, and which is supported throughout

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Appellant's disclosure and arguments in the Appeal Brief. Indeed, reading a barcode label requires interrogation by light source and detection of signal from the outside of the transparent cylinder upon which label is affixed, whereas determining a cytometric characteristic from a sample within a container requires scanning the sample itself within the containment of the transparent cylinder. However, such teaching is not reflected and recited in the rejected claims. Claims 1 and 10 instead recite, determining a cytometric characteristic of a sample disposed in a transparent cylinder which specifically does not exclude determining information incorporated into a barcode label including patient name, blood type (AB negative), diagnosis of a blood related disease (multiple myeloma having rouleaux formation of erythrocytes), albeit acquired from the same sample but subsequently disposed in the transparent cylinder.

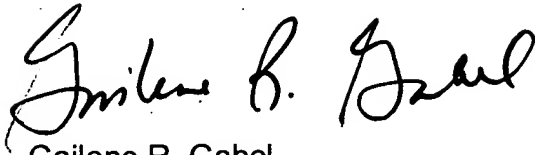
C) Appellant argues that each claim rejected under 35 USC 103(a) depends from one of independent claims 1 and 10; as Appellant contends that claims 1 and 10 are patentable, all claims dependent therefrom are also rendered patentable over the cited prior art.

In response, all rejections under 35 USC 103 (a) have been maintained because the anticipation rejections made to independent claims 1 and 10 using Nishina as primary reference, have not been overcome and are being maintained.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,



Gailene R. Gabel
May 31, 2005

Conferees

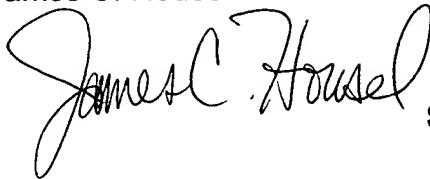
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